

ALAWAY PRESERVATIVE FREE- ketotifen fumarate solution/ drops
Bausch & Lomb Incorporated

Drug Facts

Active ingredient

Ketotifen 0.025% (equivalent to ketotifen fumarate 0.035%)

Purpose

Antihistamine

Uses

Temporarily relieves itchy eyes due to pollen, ragweed grass, animal hair and dander.

Warnings

For external use only

Do not use

- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product
- to treat contact lens related irritation

When using this product

- do not touch tip of container to any surface to avoid contamination
- discard unused portion immediately after use
- remove contact lenses before use
- does not include a preservative.

Stop use and ask a doctor if you experience any of the following:

- eye pain
- changes in vision
- redness of the eyes
- itching that worsens or lasts for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 3 years of age and older:

- twist tab completely off to open

- put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day.
- **Children under 3 years of age:** consult a doctor

Other information

- Only for use in the eye
- Store between 4°-25° C (39°-77° F).
- Use only if foil pouch is sealed and single-dose vial is intact.
- Store unused units in foil pouch.
- Protect from light.

Inactive ingredients

glycerin, hydrochloric acid and/or sodium hydroxide to adjust pH, and water for injection

Questions or comments?

[phone icon] **Call Toll Free: 1-800-553-5340**

Serious side effects associated with use of this product may be reported to this number

9677200

622243

Package/Label Principal Display Panel

NEW

PRODUCT

BAUSCH + LOMB

NDC 24208-600-01

Alaway®

Preservative Free

Ketotifen Fumarate Ophthalmic Solution 0.035%

ANTI-HISTAMINE EYE DROPS

Eye Itch Relief

UP TO

12

HOURS

Works in Minutes

Original Prescription Strength

For Ages 3 Years And Older

10 DAY SUPPLY

20 (4 pouches x five 0.4 mL) SINGLE-DOSE VIALS

Discard unused portion

STERILE

Alaway.
Preservative Free
Ketotifen Fumarate Ophthalmic Solution 0.035%
ANTIHISTAMINE EYE DROPS

SINGLE-DOSE VIALS

Eye Itch Relief

DO NOT USE IF POUCH IS TORN OR OPEN

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LOT



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24208-600	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
KETOTIFEN FUMARATE (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)		KETOTIFEN	0.35 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208-600-01	4 in 1 CARTON	09/24/2020	
1		5 in 1 POUCH		
1		0.4 mL in 1 VIAL; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA208158		09/24/2020	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment			
Name	Address	ID/FEI	Business Operations
Excelvision		274234566	MANUFACTURE(24208-600)